Wright Medical Technology, Inc.
5677 Airline Road Arlington, TN 38002
www.wmt.com

510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the WMT Implantable K-Wires.

OCT 23 2013

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	September 9, 2013
Contact Person:	Leslie Fitch Regulatory Affairs Specialist II Office - (901) 867-4120 Fax – (901) 867-4190
(a)(2). Proprietary Name:	WMT Implantable K-Wires
Common Name:	Pin, Fixation, Smooth
Classification Name and Reference:	21 CFR 888.3040 – Class II
Device Product Code, Device Panel:	HTY: Pin, Fixation, Smooth
(a)(3). Predicate Device:	K101165, K120645 Pro-Toe VO Hammertoe Implant System and K022599 NEWDEAL K WIRE

(a)(4). Device Description

The WMT Implantable K-Wires are offered in surgical grade stainless steel. A range of diameters are offered from the manufacturer and planning should be conducted prior to implantation to determine the best fit.

(a)(5). INTENDED USE

The WMT Implantable K-Wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, WMT Implantable K-Wires are indicated for the fixation of osteotomies and

reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

(a)(6). Technological Characteristics Comparison

The WMT Implantable K-Wires are technologically substantially equivalent to the predicate.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

- Through mechanical analysis the new wires do not represent a new worst-case. A literature summary was provided to support the modified indications.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject wires can be expected to perform at least as well as the predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 23, 2013

Wright Medical Technology, Incorporated
Ms. Leslie Fitch
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K132895
Trade/Device Name: WMT Implantable K-Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: September 9, 2013
Received: September 16, 2013

Dear Ms. Fitch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132895

Device Name: WMT Implantable K-Wires

Indications For Use:

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Prescription Use **xxx** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Elizabeth L. Frank -S

Division of Orthopedic Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)
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